FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
March 12, 2012

Meeting Agenda

The committee will discuss the anti-nerve growth factor (anti-NGF) drug class that is currently under development and the safety issues possibly related to these drugs. These drugs are being developed for the treatment of a variety of chronic painful conditions including osteoarthritis, chronic lower back pain, diabetic peripheral neuropathy, post-herpetic neuralgia, chronic pancreatitis, endometriosis, interstitial cystitis, vertebral fracture, thermal injury, and cancer pain. The committee will be asked to determine whether reports of joint destruction represent a safety signal related to the anti-NGF class of drugs, and whether the risk benefit balance for these drugs favors continued development of the drugs as analgesics.

8:00 a.m.	Call to Order and Introduction of Committee	**Lenore Buckley, M.D.** Chair, AAC
8:05 a.m.	Conflict of Interest Statement	**Philip Bautista, Pharm.D.** Designated Federal Officer, AAC
8:10 a.m.	FDA Introductory Remarks	**Bob Rappaport, M.D.** Director Division of Anesthesia, Analgesia and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**INDUSTRY PRESENTATIONS**	
	Introduction	**Ken Verburg, Ph.D.** Senior Vice President Medicines Development Group Pfizer, Inc.
	Perspectives on Chronic Pain	**Tom Schnitzer, M.D., Ph.D.** Professor of Medicine Northwestern University, Feinberg School of Medicine
	Tanezumab	**Ken Verburg, Ph.D.**
	Fulranumab	**David Upmalis, M.D.** Senior Director, Neuroscience Janssen Research and Development, L.L.C.
	REGN475	**Ned Braunstein, M.D.** Executive Director, Regulatory Regeneron Pharmaceuticals, Inc.
	Concluding Remarks	**Nathaniel Katz, M.D.** President, Analgesic Solutions

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Meeting Agenda (cont.)

10:15 a.m.	Clarifying Questions to Industry	
10:30 a.m.	**BREAK**	
10:45 a.m.	**FDA PRESENTATION**	
	The Natural History of Osteoarthritis and Potential Causes of Joint Destruction	**Janet W. Maynard, M.D., M.H.S.** Clinical Reviewer Division of Pulmonary, Allergy, and Rheumatology Products ODE II, OND, CDER, FDA
	Anti-NGF Drug Class Efficacy and Safety	**Anjelina Pokrovnichka, M.D.** Medical Officer, DAAAP ODE II, OND, CDER, FDA
	CDRH Adjudication Review	**Nona T. Colburn, M.D.** Medical Officer Restorative Devices Branch Division of Surgical, Orthopedic, and Restorative Devices Office of Drug Evaluation Center for Devices and Radiological Health (CDRH), FDA
12:00 p.m.	**LUNCH**	
1:00 p.m.	**SPEAKER PRESENTATION**	
	Adverse Articular Events in Studies of Anti-NGF Agents	**Joan M. Bathon, M.D.** Professor of Medicine Director, Division of Rheumatology Columbia University College of Physicians and Surgeons
1:25 p.m.	Clarifying Questions to the FDA and Speaker	
1:45 p.m.	Open Public Hearing Session	
2:45 p.m.	**BREAK**	
2:55 p.m.	Charge to the Committee	
3:00 p.m.	Questions to the Committee/Committee Discussion	
5:30 p.m.	**ADJOURNMENT**	